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Analyst Warns Soaring Market for Ketamine a 'Wild West' for Doctors and Patients

Between 500-750 ketamine clinics have cropped up across the U.S., as off-label use of ketamine hydrochloride for depression and anxiety gains in popularity. But one analyst likened doctors' use of the drug, implicated in the death of actor Matthew Perry, to a "Wild West" scenario.

By KFF Health News

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By Dawn Megli

In late 2022, Sarah Gutilla's treatment-resistant depression had grown so severe, she was actively contemplating suicide.

Raised in foster care, the 34-year-old's childhood was marked by physical violence, sexual abuse and drug use, leaving her with life-threatening mental scars.

Out of desperation, her husband scraped together $600 for the first of six rounds of intravenous ketamine therapy at Ketamine Clinics Los Angeles, which administers the generic anesthetic for off-label uses such as treating depression.

When Gutilla got into an Uber for the 75-mile drive to Los Angeles, it was the first time she had left her home in Llano, California, in two years. The results, she said, were instant.

"The amount of relief I felt after the first treatment was what I think 'normal' is supposed to feel like," she said. "I've never felt so OK, and so at peace."

For-profit ketamine clinics have proliferated over the past few years, offering infusions for a wide array of mental health issues, including obsessive-compulsive disorder, depression and anxiety.

Although the off-label use of ketamine hydrochloride, a Schedule III drug approved by the U.S. Food and Drug Administration (FDA) as an anesthetic in 1970, was considered radical just a decade ago, now between 500 and 750 ketamine clinics have cropped up across the nation.

Market researcher Grand View Research pegged industry revenues at $3.1 billion in 2022 and projects them to more than double to $6.9 billion by 2030. Most insurance doesn't cover ketamine for mental health, so patients must pay out-of-pocket.

While it's legal for doctors to prescribe ketamine, the FDA hasn't approved it for mental health treatment, which means that individual practitioners must develop their own treatment protocols.

The result is wide variability among providers, with some favoring gradual, low-dosage treatments while others advocate larger amounts that can induce hallucinations, as the drug is psychedelic at the right doses.

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"Ketamine is the wild West," said Dustin Robinson, the managing principal of Iter Investments, a venture capital firm specializing in hallucinogenic drug treatments.

Ketamine practitioners stress that the drug's emergence as a mental health treatment is driven by a desperate need. Depression is the leading cause of disability in the U.S. for individuals ages 15-44, according to the National Institute of Mental Health, and around 25% of adults experience a diagnosable mental disorder in any given year.

Meanwhile, many insurance plans cover mental health services at lower rates than physical health care, despite laws requiring parity.

Thus many patients with disorders receive little or no care early on and are desperate by the time they visit a ketamine clinic, said Steven Siegel, chair of psychiatry and the behavioral sciences at the University of Southern California's Keck School of Medicine.

But the revelation that "Friends" star Matthew Perry died in part from a large dose of ketamine, along with billionaire Elon Musk's open use of the drug, has piqued fresh scrutiny of ketamine and its regulatory environment, or lack thereof.

Commercial ketamine clinics often offer same-day appointments, in which patients can pay out-of-pocket for a drug that renders immediate results.

The ketamine is administered intravenously, and patients are often given blankets, headphones, and an eye mask to heighten the dissociative feeling of not being in one's body.

A typical dose of ketamine to treat depression, which is 10 times lower than the dosage used in anesthesia, costs clinics about $1, but clinics charge $600-$1,000 per treatment.

Ketamine is still shadowed by its reputation as the party drug known as "Special K"; Siegel's first grant from the National Institutes of Health was to study ketamine as a drug of abuse.

It has the potential to send users down a "K hole," otherwise known as a bad trip, and can induce psychosis. Research in animals and recreational users has shown chronic use of the drug impairs both short- and long-term cognition.

Perry's death in October 2023 raised alarms when the initial toxicology screening attributed his death to the acute effects of ketamine.

A December 2023 report revealed Perry received infusion therapy a week before his death but that the fatal blow was a high dose of the substance taken with an opioid and a sedative on the day of his death — indicating that medical ketamine was not to blame.

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A variety of protocols

Sam Mandel co-founded Ketamine Clinics Los Angeles in 2014 with his father, Steven Mandel, an anesthesiologist with a background in clinical psychology, and Sam said the clinic has established its own protocol.

That includes monitoring a patient's vital signs during treatment and keeping psychiatrists and other mental health practitioners on standby to ensure safety. Initial treatment starts with a low dose and increases as needed.

While many clinics follow the Mandels' graduated approach, the dosing protocol at MY Self Wellness, a ketamine clinic in Bonita Springs, Florida, is geared toward triggering a psychedelic episode.

Christina Thomas, president of MY Self Wellness, said she developed her clinic's procedures against a list of "what not to do" based on the bad experiences people have reported at other clinics.

The field isn't entirely unregulated: State medical and nursing boards oversee physicians and nurses, while the FDA and Drug Enforcement Administration regulate ketamine.

But most anesthesiologists don't have a background in mental health, while psychiatrists don't know much about anesthesia, Sam Mandel noted.

He said a collaborative, multidisciplinary approach is needed to develop standards across the field, particularly because ketamine can affect vital signs such as blood pressure and respiration.

The protocols governing Spravato, an FDA-approved medication based on a close chemical cousin of ketamine called esketamine, are illustrative.

Because it has the potential for serious side effects, it falls under the FDA's Risk Evaluation and Mitigation Strategies (REMS) program, which puts extra requirements in place, said Robinson.

Spravato's REMS requires two hours of monitoring after each dose and prohibits patients from driving on treatment days.

Generic ketamine, by contrast, has no REMS requirements. And because it is generic and cheap, drugmakers have little financial incentive to undertake the costly clinical trials that would be required for FDA approval.

That leaves it to the patient to assess ketamine providers. Clinics dedicated to intravenous infusions, rather than offering the treatment as an add-on, may be more familiar with the nuances of administering the drug.

Ideally, practitioners should have mental health and anesthesia expertise or have multiple specialties under one roof, and clinics should be equipped with hospital-grade monitoring equipment, Mandel said.

Siegel, who has researched ketamine since 2003, said the drug is especially useful as an emergency intervention, abating suicidal thoughts for long enough to give traditional treatments, like talk therapy and SSRI antidepressants, time to take effect.

"The solutions that we have and have had up until now have failed us," Mandel said.

The drug is now popular enough as a mental health treatment that the name of Mandel's clinic is a daily sight for thousands of Angelenos as it appears on 26 Adopt-A-Highway signs along the 405 and 10 freeways.

And the psychedelic renaissance in mental health is accelerating.

A drug containing MDMA, known as ecstasy or molly, is expected to receive FDA approval in 2024. A drug with psilocybin, the active ingredient in "magic mushrooms," could launch as early as 2027, the same year a stroke medicine with the active ingredient of DMT, a hallucinogen, is expected to debut.

Robinson said many ketamine clinics have opened in anticipation of the expanded psychedelic market.

Since these new drugs will likely be covered by insurance, Robinson advises clinics to offer FDA-approved treatments such as Spravato so they'll have the proper insurance infrastructure and staff in place.

For now, Sarah Gutilla will pay out-of-pocket for ketamine treatments. One year after her first round of infusions, she and her husband are saving for her second.

In the meantime, she spends her days on her ranch in Llano where she rescues dogs and horses and relies on telehealth therapy and psychiatric medications.

While the infusions aren't "a magic fix," they are a tool to help her move in the right direction.

"There used to be no light at the end of the tunnel," she said. "Ketamine literally saved my life."

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If you have not suffered long-term chronic pain or depression, you have no idea how a drug like ketamine can virtually or literally save your life. All these value judgements are irrelevant to the experience and needs of actual people who are suffering. No treatment is right for all patients, but having chronic pain, having researched ketamine heavily and having taken it for years, I can tell you that folks who are not having these conditions should not be dictating to others what treatments they should or could have.
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